Supreme Court, U.S.
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No.

In The

Supreme Court of the United States

October Term, 1996

CARL OLSEN,

Petitioner,

vs.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia

PETITION FOR WRIT OF CERTIORARI

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106 pp

QUESTIONS PRESENTED

1. Did the Drug Enforcement Administration improperly reject Petitioner's petition to have marijuana rescheduled from Schedule I to Schedule II of the Controlled Substances Act of 1970, and whether that rejection was arbitrary and capricious and contrary to law?

2. Did the Drug Enforcement Administration violate Petitioner's rights under the First Amendment to the United States Constitution to petition the government for a redress of grievances, and thus his Fifth Amendment right to due process, by summarily dismissing his petition to have marijuana rescheduled from Schedule I to Schedule II of the Controlled Substances Act of 1970 without a proper hearing?

3. Did the Drug Enforcement Administration violate Petitioner's Fifth Amendment procedural due process rights by summarily dismissing his petition to have marijuana rescheduled from Schedule I to Schedule II of the Controlled Substances Act of 1970 without a proper hearing?

4. Did the Drug Enforcement Administration violate Petitioner's right to privacy, interfering with sensitive medical decisions without proper constitutional justification, by summarily dismissing his petition to have marijuana rescheduled from Schedule I to Schedule II of the Controlled Substances Act of 1970 without a proper hearing?

5. Did the Drug Enforcement Administration violate Petitioner's right to equal protection of the laws, invalidly treating legal medical Marinol patients differently from illegally smoked marijuana patients without a rational basis, by summarily dismissing his petition to have marijuana rescheduled from Schedule I to Schedule II of the Controlled Substances Act of 1970 without a proper hearing?

PARTIES TO THE PROCEEDING

The parties to the proceeding in the United States Court of Appeals for the District of Columbia are those in the caption.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner herein respectfully prays that a writ of certiorari issue to review the judgement of the United States Court of Appeals for the District of Columbia entered on October 3, 1996.

OPINIONS BELOW

The decision of the United States Court of Appeals for the District of Columbia is unreported, (94-1605 D.C. Cir. October 3, 1996). (1a). The final order of the Drug Enforcement Administration is also unreported, (93-1109 D.C. Cir. May, 16, 1994). (3a).

STATEMENT OF JURISDICTION

The final order of the court of appeals was entered on October 3, 1996. The court of appeals had jurisdiction over this matter pursuant to 21 U.S.C. § 877. This Court has jurisdiction to review the judgement of the court of appeals pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

Pursuant to Rule 14(f) of the Supreme Court Rules, the citation of relevant constitutional, statutory, and regulatory provisions involved are listed here, while the pertinent text is set out in the appendix to this petition at pages 8-23.

First, Fifth, Ninth and Fourteenth Amendments to the United States Constitution.

5 U.S.C. § 706; 21 U.S.C. § 811; 21 U.S.C. § 812; 21 U.S.C. § 877; 21 C.F.R. § 1307.03; 21 C.F.R. § 1308.11; 21 C.F.R. § 1308.12; 21 C.F.R. § 1308.44; 28 C.F.R. § 0.100(b); 28 C.F.R. § 0.104.

STATEMENT OF THE CASE

A. Statutory And Regulatory Background.

In 1970 Congress passed the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("C.S.A."). The C.S.A. classifies various substances into five schedules. 21 U.S.C. § 812. Restrictions upon use and access to a particular drug vary based upon the drug's schedule status in the C.S.A. *Id.* Drugs in Schedule I are subject to more severe restrictions than drugs in the other schedules. *See Alliance for Cannabis Therapeutics (hereinafter "A.C.T.") v. Drug Enforcement Administration (hereinafter "D.E.A.")*, 930 F.2d 936, 937 (D.C. Cir. 1991). Congress placed marijuana in schedule I of the C.S.A. 21 U.S.C. § 812(c), schedule I(c)(10).

Although Congress made the initial scheduling decisions, the C.S.A. specifically permits the Attorney General to add a substance to a schedule, transfer a substance from one schedule to another or remove a substance from the schedules entirely. 21 U.S.C. § 811(a)(1).[1]

---

1. Under the C.S.A., a drug or substance may not be placed in schedule II absent findings that:

> (A) The drug or other substance has a high potential for abuse;
>
> (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions;
>
> (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence. 21 U.S.C. § 812(b)(2)(A)-(C).

The Attorney General may only add or transfer a substance to a different schedule if she "finds that such drug or other substance has a potential for abuse" and makes findings that the drug or substance meets the requirements for the new schedule. *See* 21 U.S.C. § 811 (1)(a) and (b). Section 812(b) of Article 21 of the United States Code sets out the findings required to place a substance in a particular schedule. 21 U.S.C. § 812(b). The Attorney General has delegated the authority to reschedule controlled substances to the Administrator of the D.E.A. 28 C.F.R. § 0.100(b). The Drug Enforcement Administrator (hereinafter "Administrator") has further delegated this authority to the Deputy Administrator of the D.E.A. 28 C.F.R. § 0.104.

The C.S.A. provides that any interested party may petition to have a substance added to, removed or transferred between the controlled substance schedules. 21 U.S.C. § 811(a)(2). Any rules promulgated under this subsection are subject to the rule making procedures of the administrative Procedures Act found in Title 5. 21 U.S.C. § 811(a)(2); 5 U.S.C. § 5 (subchapter II). Pursuant to Title 5, a reclassification rule promulgated under § 811(a)(1) must be made on the record after opportunity for hearing. *National Organization For the Reform of Marijuana Laws (hereinafter "NORML") v. D.E.A.*, 559 F.2d 735, 738 n. 9 (1977). The administrator of the D.E.A. is obligated to respond to all petitions for the issuance, amendment or repeal of rules pursuant to 21 U.S.C. § 811 and by 21 C.F.R. § 1308.44(c) which provides that within a reasonable time after the receipt of a petition, the administrator shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted reasons therefore. This obligation pertains whether or not the object of the petition falls within the scope of 21 U.S.C. § 811. 21 C.F.R. § 1308.44(c).

Section 811(b) of Article 21 of the United States Code, titled Evaluation of Drugs and Other Substances, clearly states that

the Attorney General must, after gathering all the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled. 21 U.S.C. § 811(b). These recommendations are binding upon the Attorney General. *Id.* The clear mandate of the statute and case precedent make it clear that the D.E.A. is not authorized to make scientific and medical findings regarding the scheduling of substances without advice from the Secretary of HEW (now H.H.S.) or their delegatee, FDA. *NORML*, 559 F.2d at 738. For example, the D.E.A. must defer to H.H.S. for scientific and medical findings regarding the structure of a drug. 21 U.S.C. § 811(b)

The D.E.A.'s stubborn refusal to exercise its authority to reschedule marijuana has resulted in an arduous legal history of orders and remands. *See Alliance for Cannabis Therapeutics (hereinafter "A.C.T.") v. D.E.A.*, 15 F.3d 1131 (D.C. Cir. 1994); *A.C.T.*, 930 F.2d at 937; *NORML v. D.E.A.*, 559 F.2d 735 (D.C. Cir. 1977); *NORML v. Ingersoll*, 497 F.2d 654 (D.C. Cir. 1974).

These cases originated from one petition filed with the Bureau of Narcotics and Dangerous Drugs (BNDD), predecessor to the D.E.A. On May 18, 1972 NORML filed the petition seeking to have marijuana removed from the C.S.A. or in the alternative transferred to schedule II. *NORML*, 497 F.2d at 655. As a result of BNDD's refusal to accept the petition for filing, NORML sued. *Id.* at 656. The Court of Appeals ordered the D.E.A. to accept the petition and respond on the merits. *Id.* at 661. Thereafter, D.E.A. Administrator skirted the statutorily mandated recommendation from the secretary of HEW, ignored the findings of Administrative Law Judge Parker and denied the petition in all respects. 40 Fed. Reg. 44164, 44168 (1975); *NORML*, 559 F.2d at 742-43. The Court of Appeals again remanded the petition back to the D.E.A. with an order to refer the petition to the Secretary of HEW for medical and scientific

findings and recommendations for rescheduling. *NORML*, 559 F.2d at 757.

Forced to follow proper procedure, D.E.A. issued a notice of a hearing on the rescheduling petition in 1986. *See* 51 Fed. Reg. 22,946 (1986). Administrative Law Judge Young conducted extensive proceedings and found that marijuana enjoyed a current accepted medical use and therefore could be placed in schedule II. *A.C.T.*, 930 F.2d at 938. Rejecting the evidence and disagreeing with Judge Young's conclusions, the D.E.A. Administrator reaffirmed his prior order stating that marijuana should not be moved from schedule I because the marijuana plant has no currently accepted medical use. *See* 54 Fed. Reg. 53,767, 53,784 (1989). In making this determination, previous Administrator Lawn listed several criteria used for determining accepted medical use, and declared that marijuana failed to meet them. *See* 57 Fed. Reg. at 10,507-10,508.

As the issue became more narrowly focused, A.C.T. became the lead petitioner in the case. A.C.T., and other parties seeking rescheduling, advanced the argument that pursuant to 21 U.S.C. § 812(b)(2)(B), marijuana has an accepted medical use in the United States and therefore should be rescheduled. *See A.C.T.*, 930 F.2d at 939.

A.C.T. appealed the order for a second time. The Appeals Court remanded the case yet again on the grounds that the criteria the Administrator used to determine currently accepted medical use were impossible to satisfy. *See A.C.T.*, 930 F.2d at 940-941.

Reconsidering the issue yet again, the new Administrator explained that the prior Administrator had not relied on two of the three impermissible criteria and clarified the third criteria. 57 Fed. Reg. 10,507, 10,499 (1992); *A.C.T. v. D.E.A.*, 15 F.3d 1131 (D.C. Cir. 1994). According to Administrator Bonner, the

two criteria not considered were the general availability of the substance and the use of the substance by a substantial segment of medical practitioners. 57 Fed. Reg., at 10,499 (1992). He further argued that the recognition of clinical use in generally accepted pharmacopeia rested on a determination by the previous administrator that marijuana lacked a known, reproducible chemistry. *A.C.T.*, 15 F.3d at 1135. Thus, a new five part test for determining whether a drug had a currently accepted medical use was created.[2] 57 Fed. Reg at 10,506. Based on these findings he upheld the decision that marijuana plants should remain in schedule I. *Id.* The Court of Appeals upheld the Order, finding that the D.E.A. had properly clarified its test for accepted medical use. *Id.* at 10,499; *See also A.C.T.*, 15 F.3d at 1137.

As the issue proceeded through the courts, tangential consideration was given to the difference between synthetic THC and THC found naturally in marijuana. 54 Fed. Reg. at 53,774.

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2. Administrator applied a five-part test for determining whether a substance had a currently accepted medical use:

> (1) the drug's chemistry must be known and reproducible;
>
> (2) there must be adequate safety studies;
>
> (3) there must be adequate and well-controlled studies proving efficacy;
>
> (4) the drug must be accepted by a respectable minority of qualified experts; and
>
> (5) the scientific evidence must be widely available.

57 Fed. Reg. at 10,504-10,507 (1992). After reviewing the evidence in the record, the Administrator found that marijuana could not satisfy a single one of these criteria. *Id.* at 10,507.

In the Final Order on the petition, Administrator Bonner adopted the findings of former Administrator Lawn who stated there is no difference in the pharmacological effect between THC isolated from cannabis and the synthetically produced THC which is now marketed in the United States. *Id.* Administrator Lawn's conclusion concurred with prior findings made by H.H.S. that the pharmaceutical qualities of synthetic delta-9-THC are the same as those of delta-9-THC itself. *Id.* Following isolation and characterization of delta-9-THC as the major active component of marijuana by Mechoulam and colleagues, a technique for producing synthetic material was developed. Plasse, T.; Gorter, R.; Krasnow, S.; Lane, M.; Shepard, K.; Wadleigh, R. Recent Clinical Experience with Drionabinol. Pharmacology Biochemistry & Behavior, Vol. 40, pp. 695-700; 1991 (Gaoni, Y.; Mechoulam R.; neutral cannabinoids from hashish. J Am. Chem. Soc. 93; 217-224; 1971) (Petrzilaka, T.; Haefliger,W.; Sikemier, C. Synthesis of Hashish Components. Part 4. Helv. Chim. Acta 52: 1102-1134; 1969). This process was used to create the drug Marinol which is now at the heart of the present controversy. *See Id.*

By definition, a synthetic drug is the same as its natural occurring twin. (24a). Dronabinol is only one substance, not two. Adding sesame oil and encapsulating the finished recipe in soft gelatin capsules, while having significance to the Food and Drug Administration (hereinafter "F.D.A.") for marketing purposes, does not make Dronabinol into another drug for scheduling purposes. In 1986, Health and Human Services (H.H.S.) recognized that synthetic delta-9-THC is the same as its naturally occurring twin. 51 Fed. Reg. at 17,476.

B. The Current Proceedings.

On July 21, 1992, noting several inconsistencies between the Order and prior findings of fact and law, the petitioner sent a letter to then-Administrator Robert C. Bonner in which he

raised several questions about the Administrator's final order. Specifically, petitioner asked why coca and opium poppy plants are scheduled in Schedule II of the C.S.A., since both of these plants are subject to the same variances in chemistry as the marijuana plant and neither are reproducible in standardized dosages. (25a); *See* 57 Fed. Reg. 10,499.

On August 17, 1992, Administrator Bonner sent the petitioner a response to his letter. In the response, the Administrator rejected the petitioner's attempt to analogize marijuana plants to coca and opium plants. (37a). The Administrator explained that when Congress placed coca leaves and opium plant materials in Schedule II, it was aware that these plants had been recognized historically as the source for a variety of accepted and useful medications. *Id.* The plants contain medically active alkaloids that can be extracted and used to produce pharmaceutical compounds capable of reproduction in standardized doses. *Id.* In contrast, the Administrator pointed out that the recent attempts to reschedule marijuana were not grounded on claims that medically useful compounds could be extracted from marijuana, but rather that smoking marijuana itself produced medical benefits. *Id.* Thus, the Administrator found the scheduling decisions to be reconcilable. *Id.*

Interpreting the Administrator's statements regarding the scheduling of coca and opium poppy plants as general rules of statutory construction, the petitioner, proceeding pro se, then filed a formal request for the rescheduling of marijuana pursuant to 21 U.S.C. § 811 and 21 C.F.R. § 1307.03 in the form prescribed by 21 C.F.R. § 1308.44(b). The petition was based on the grounds that Dronabinol, delta-9-tetrahydrocannabinol (delta-9-THC), the principle psychoactive substance in the marijuana plant, was rescheduled to schedule II of the C.S.A. in 1986, and, therefore, because marijuana is the source of Dronabinol, it should have been moved into the same schedule

as Dronabinol.(27-28a). *See* Final Order of the Drug Enforcement Administration, May 13, 1986: 51 Fed. Reg. 17,476 (placing Dronabinol in schedule II).

In an order dated May 16, 1992, Deputy Administrator Greene refused to accept the petition for filing on the basis of his finding that Dronabinol is a wholly synthetic substance and is not obtained from marijuana. Despite refusing to accept the petition for filing, the administrator proceeded to reject the issues raised in the petition on their merits. The Deputy Administrator responded to the petition stating only the pharmaceutical product was transferred from schedule I to schedule II, *i.e.*, Dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product. No rescheduling action was taken with regard to (-) delta-9-trans-THC, i.e., Dronabinol, which remains in Schedule I of the C.S.A. The Deputy Administrator further explained under the C.S.A., the regulation of chemicals and the plant material are distinct from each other. The classification of delta-9-THC has no bearing on the classification of marijuana. Under the C.S.A., a proposed change in the schedule of either a tetrahydrocannabinol or the plant marijuana requires the Attorney General to proceed independently. *See* 21 U.S.C. § 811.

Petitioner appealed the Deputy Administrator's denial of the petition to the Circuit Court of Appeals for the District of Columbia Circuit. *Olsen v. D.E.A.*, No. 93-1109 (D.C. Cir. Dec. 9, 1993). Familiar with Appellate Court frustration toward the D.E.A. in such matters, the D.E.A. requested a remand for a formal ruling on the petition. Order dated December 9, 1993. *See Olsen v. D.E.A.*, No. 93-1109 (D.C. Cir. Dec. 9, 1993).

Without seeking advice from the Secretary of Health and Human Services, (hereinafter "H.H.S.") Deputy Administrator Stephen H. Greene issued a eight-page Final Order denying the

petition. (3a-10a). In the Final Order Mr. Greene rejected the petitioner's analogy, finding that marijuana can only be moved from schedule I if there is a finding that marijuana has a "currently accepted medical use in treatment in the United States." (7a). The order acknowledged that (-) delta-9-trans-THC isomer, the principal psychoactive ingredient in marijuana, is also the ingredient in a pharmaceutical product that has proven to be a safe and effective anti-emetic for patients receiving cancer chemotherapy. *Id.* Even so, only a very specific synthetic Dronabinol product was rescheduled to schedule II — "Dronabinol" (synthetic) in sesame oil and encapsulated in a soft gelatin capsule" in a drug product approved by the Food and Drug Administration (hereinafter "F.D.A."). (7a-8a).

According to his interpretation of the statute, Administrator Greene further stated that the regulation of plants and chemicals under the C.S.A. is distinct and that the C.S.A. requires the independent evaluation of each individual controlled substance. Thus he concluded, because marijuana plants have no currently accepted medical use in treatment, the rescheduling of one pharmaceutical product did not require D.E.A. to transfer marijuana plants or any other substance to schedule II. (7a-8a).

Pursuant to 21 U.S.C. § 877, the petitioner appealed the Final Order to the Circuit Court of Appeals. On October 6, 1996 the court affirmed the D.E.A.'s denial of Mr. Olsen's petition without opinion. (1a).

REASONS FOR GRANTING THE WRIT

I.

JUDICIAL REVIEW OF ADMINISTRATIVE PROCESS.

Under the Controlled Substances Act, decisions made by the Drug Enforcement Administrator, with regard to scheduling rules made pursuant 21 U.S.C. § 811(a), are subject to review pursuant to 21 U.S.C. § 877 and 5 U.S.C. § 706. While it is true that the court's role in reviewing administrative decisions is limited, the doctrine of deference to agency rulings clearly has limits. *NLRB v. Brown*, 380 U.S. 278, 291 (1965); *Wheatley v. Adlee*, 407 F.2d 307, 310 (D.C. Cir. 1968). Courts should only defer to administrative experience where an agency acts within its discretionary powers, under the law. *International Brd. Of Elec. Wkrs v. NLRB*, 487 F.2d 1143, 1170-71 (D.C. Cir. 1973), *aff'd sub nom., Florida Power & Light Co. v. International Brd. Of Elec. Wkrs.*, 417 U.S. 790 (1974).

However, such discretion must not be given in support of actions taken outside of the law. *Id.* at 1171. Court must determine what administrative action falls within the law, for no agency is a law unto itself. *See Id.; Brown*, 380 U.S. at 291 (Courts must be vigilant to ensure that the agency's procedures and underlying standards are in accord with the law).

An administrative decision must be set aside if it either rests on factual premises which are not based on substantial evidence or if the underlying standards on which the decision is based is not in accord with the law. *Wheatley*, 407 F.2d at 310. This is especially true where the improper administrative decision is inconsistent with statutory mandate or where it frustrates the Congressional policy underlying a statute. *Id.* Where an administrator exercises discretion in violation of the law, the

court owes no deference to the decision and may set it aside. *NORML v. D.E.A.*, 559 F.2d at 754.

A. Certiorari Should Be Granted To Consider Whether The Final Order Should Be Set Aside Because The Decision Was Made Without The Procedure Required By Law.

The Final Order of Deputy Administrator Green should be held unlawful and set aside because Deputy Administrator Green exceeded the scope of his authority under § 201(a)of the C.S.A. when he denied Petitioner Olsen's rescheduling petition without first obtaining a medical and scientific evaluation and recommendation from the Secretary of Health Education and Welfare (hereinafter "H.E.W."). 21 U.S.C. § 811(a); 5 U.S.C. § 706(d); *NORML*, 559 F.2d at 738. The D.E.A.'s rescheduling power is subject to the limitations proscribed by the Administrative Procedures Act (hereinafter "A.P.A.") 21 U.S.C. § 811(b); 5 U.S.C. § 706. Under the A.P.A. an agency action taken in excess of proscribed statutory authority can be set aside and held unlawful. 5 U.S.C. § 706.

While a reviewing court should grant some deference to an agency's interpretation of the statute under which it operates, this deference is constrained by an obligation to honor the clear meaning of a statute as revealed by the language, purpose and history of the statute. *See, Teamsters v. Daniel,* 336 U.S. 551, 556 n. 20 (1979); *Southeastern Community College v. Davis*, 442 U.S. 397, 411 (1979): *Brookline v. Gorsuch*, 667 F.2d 215, 219 (1st Cir. 1981). 21 U.S.C. § 811(b), clearly requires the Administrator, prior to the commencement of reclassification rule making proceedings under subsection section (a), to request from the Secretary a scientific and medical evaluation, along with the Secretary's recommendations as to whether such drug or other substance should be so controlled or removed as a controlled substance. 21 U.S.C. § 811(b); *NORML*, 559 F.2d at 754. Pursuant to § 201(b), the Secretary's recommendations shall

be binding on the Administrator as to such scientific and medical matters. 21 U.S.C. § 811(b). If the secretary recommends that a drug or other substance not be controlled then the Administrator shall not control the drug or other substance. 21 U.S.C. § 811(b). Both D.E.A. and H.E.W. have interpreted this section to bar the D.E.A. from exceeding the level of control recommended by H.E.W. *NORML*, 559 F.2d at 738 n. 11.

In addition to ignoring the clear language of the statute, D.E.A.'s denial of the petition without seeking the advice of H.E.W went against established case precedent and Congressional policy. *Id.* at 745. In previous rescheduling cases, the courts have repeatedly held that D.E.A. is required to seek the input of H.E.W. before making scheduling determinations. *Id.*[3] In reaching this conclusion, courts have reviewed the statutory history and record of the C.S.A. and found that Congress strongly disfavored placing too much control into the Attorney General's hands. *NORML*, 559 F.2d at 744-48. As the Congressional record demonstrates, Congress sought to have the D.E.A. use H.E.W.'s vast scientific and medical resources to make scheduling decisions rather than relying the Administrator's personal opinions. *See NORML*, 559 F.2d at 746. Statements found in the Senate report made regarding the C.S.A. show the commonly held belief, by members of both houses, that the D.E.A. is simply not qualified to make such important medical and scientific decisions.[4] *See Id.* at n. 47. Just as in

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3. *See e.g., A.C.T. v. D.E.A.*, 15 F.3d 1131 (1994); *A.C.T., et al. v. D.E.A.*, 930 F.2d 936 (1991); *NORML v. D.E.A.*, 559 F.2d 735 (1977); *NORML v. Ingersoll*, 497 F.2d 654 (1974). As the history of this controversy clearly demonstrates the D.E.A has repeatedly made medical and scientific determinations without the advice of H.E.W. *NORML*, 559 F.2d at 741; *NORML v. Ingersoll*, 497 F.2d 654.

4. As one legislator noted, This title vests the authority for control of the substances enumerated under its provision with the Attorney General. (Cont'd)

1977, the failure of the Deputy Administrator to follow the spirit and the letter of the law in handling Mr. Olsen's petition amounts to the destruction of the balance of power created by a deliberate and conscientious exercise of the legislative process. *See, Id.* at 746; *Wheatley,* 407 F.2d at 310.

The D.E.A.'s refusal to follow proper rule making procedure is suspect, in consideration of the reclassification of synthetic THC to schedule II. *See* 51 Fed. Reg. 17476. The D.E.A. does not have authority to impose schedule I controls on a drug which has been approved for medical use by the Food and Drug Administration (hereinafter "F.D.A.") *Grinspoon, M.D. v. D.E.A.*, 828 F.2d 881,890 (1st. Cir. 1987) *c.f.*, 1984 U.S. Cong. & Admin. News 540, 543. The failure of Deputy Administrator Green to seek advice, as required under the C.S.A., from the Secretary of Health and Human Services may be due to the fact that the F.D.A. has granted a new drug application for Marinol, a prescription drug product containing THC. 51 Fed. Reg. 17476. H.H.S. previously notified D.E.A. that should F.D.A. approve THC for a new drug application, marijuana should be rescheduled to schedule II. 50 Fed. Reg. 42186. Since the F.D.A. has approved THC for a new drug application, D.E.A. is required to follow the Secretary of Health's recommendation. 21 U.S.C. § 811.

(Cont'd)

There has been a point of controversy evident among the professionals involved in drug control and drug research on whether or not the Justice Department has the expertise to schedule or reschedule drugs since such decisions require special medical knowledge and training. *NORML*, 559 F.2d at 746. The Senate report further noted that the provision which requires the D.E.A. to follow H.E.W. advice during scheduling proceedings alleviates this difficulty. S. Rep. No. 91-613, H.R. Rep. No. 91-1444, 91st Cong., 2d sess., pt. 1, at 5, U.S. Code Cong. & Admin. News 1970, pp. 4566, 4569 (1970).

B. The Court Should Grant Certiorari To Consider Whether The D.E.A.'s Statutory Interpretation Is Inconsistent With The Law And Whether Based Upon Its Misinterpretation, It Exceeded Its Statutory Authority.

This Court is not required to defer to agency statutory construction where that construction is inconsistent with the letter of the law. *See St. Mary of Nazareth Hospital Center v. Schweiker*, 718 F.2d 459 (D.C. Cir. 1983), *on remand*, 587 F. Supp. 937 (D.D.C. 1984). Claiming to have authority pursuant to 21 C.F.R. § 1308.44(c), Deputy Administrator Green denied the petition based upon his findings that the grounds upon which petitioner relied were not sufficient to justify the initiation of rescheduling proceedings.[5] (10a). Other courts have previously warned the D.E.A. that the outright rejection of a rescheduling petition is a preemptory action, soundly used only in the clear case of a filing either patently deficient in form or a substantive nullity. *NORML*, 497 F.2d at 659; *Municipal Light Boards v. FPC*, 450 F.2d 1341,1345 (D.C. Cir. 1971), *cert. denied*, 405 U.S. 989 (1972). The court further cautioned that the use of the preemptory challenge should not be used to dispose of a matter on the merits. *Municipal Light Boards*, 450 F.2d at 1346. In very limited cases, a rejection of a petition on the merits may be taken without invoking formal rule making proceedings when issues of law are decisive and can be decided without taking testimony or hearing the views of others involved. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 621 (1973); *Citizens for Allegan County, Inc. v. FPC*, 414 F.2d 1125, 1129 (D.C. Cir. 1969). The Administrator's technical arguments in the Final Order prove that this was not a clear cut case involving decisive issues of law. (3a-10a); *See Id.* Because the petition involved technical scientific and legal questions, the administrator acted without authority in denying the petition on

5. As the language of the regulation reads, if accepted for filing a petition may be denied if the Administrator finds the grounds upon which the petitioner relied are not sufficient to justify the initiation of proceedings.

the merits. *See* 21 U.S.C. § 811(b); *NORML*, 559 F.2d at 741.

The Administrator also exceeded the scope of his statutory authority when he ignored the evidence presented by Mr. Olsen. 21 U.S.C. § 811(a); *Weinberger*, 412 U.S. at 620; *United States v. Alexander*, 673 F.2d 287 (9th Cir. 1982); *NORML*, 559 F.2d at 741. Due to the evidence that a D.E.A. scheduling decision was possibly in conflict with an H.E.W. recommendation, the D.E.A. was required to consult with and follow H.E.W.'s recommendations regarding the merits of the petition. (3a-10a). *See also* 21 U.S.C. § 811(b); 50 Fed. Reg. 42186; *NORML*, 497 F.2d at 659.[6] Completely ignoring this evidence, the D.E.A. denied the petition on the grounds that Mr. Olsen presented no new medical, scientific or other information. (7a-8a).[7] The failure to consider this new evidence was beyond the scope of the Administrator's authority. 21 U.S.C. § 811(a).

C. The Court Should Grant Certiorari To Consider Whether The Administrator's Findings Were Contrary To The Law.

The D.E.A.'s finding that the rescheduling of synthetic Dronabinol encapsulated in sesame oil has no bearing on the rescheduling of marijuana contradicts case precedent and therefore is incorrect as a matter of law. *See* 40 Fed. Reg. 44167, 44168 (1974); *NORML*, 559 F.2d at 742, 757. The chemical delta-9-tetrahydrocannabinol (THC) is the principal psychoactive substance in cannabis materials and is the reason the marijuana plant is subject to control under the CSA. 40 Fed. Reg. 44166 (1975); *United States v. Walton*, 514 F.2d 201, 202-

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6. Despite this clearly stated position, Administrator Green simply ignored the letter.(3a-10a). Poignantly, no mention of this letter is ever made in the respondent's brief to the Appeals Court. *Id.*

7. Despite this contention, D.E.A. Deputy Administrator Green proceeded to deny Mr. Olsen's petition by analyzing the scientific and medical issues Mr. Olsen had noted in his petition.

04 (D.C. Cir. 1975). In prior cases, D.E.A. was required to consider the scheduling of "synthetic THC" along with its consideration of rescheduling marijuana. *NORML*, 559 F.2d at 757. The court found that the D.E.A. was estopped from arguing that NORML was required to file a separate petition to reschedule synthetic THC because D.E.A. did not contend it had been prejudiced when synthetic THC was discussed at rescheduling hearings. *Id.* Furthermore, the court found that the D.E.A. had failed to argue that the differences between the synthetic THC and natural marijuana were too great to warrant consolidated consideration. *Id.* Based upon this precedent, the D.E.A. cannot now properly argue that synthetic THC and the THC found in marijuana are not related. *See* Respondent's Brief (38a-40a). This finding should be set aside on the grounds that it contradicts prior case law. 5 U.S.C. § 706.

D. The Court Should Grant Certiorari To Consider Whether The D.E.A.'s Denial Of The Rescheduling Petition Was Made Arbitrarily And Capriciously.

Under the A.P.A., an administrative decision made arbitrarily or capriciously may be set aside. 5 U.S.C. § 706(a); *Chevron U.S.A. Inc.v. Natural Resources Defense Council*, 467 U.S. 837, 843-44 (1984). The D.E.A.'s unjustified change of position with respect to synthetic versus natural THC reveals the arbitrary and capricious manner in which Mr. Olsen's petition was denied. 5 U.S.C. § 706(a). *See Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1977); *Skidmore v. Swift*, 323 U.S. 134, 140 (1944). Under the arbitrary and capricious standard, the D.E.A. is required to expressly justify any departure from earlier regulatory approaches. *See, FORMULA v. Heckler*, 779 F.2d 743, 760 (D.C. Cir. 1985); 771 F.2d 233, 242 (D.C. Cir 1983). Furthermore, the D.E.A. is required to provide a reasoned justification for the departure or the decision will be found arbitrary and capricious. *Heckler*, 779 F.2d at 760.

Throughout the history of the rescheduling cases the D.E.A. has repeatedly changed position on important issues without justifying such departures. *Id.*; *NORML*, 559 F.2d at 746; *NORML*, 497 F.2d at 659. Previously, D.E.A. Administrator Bonner explained that schedule II drugs were defined as scientifically established chemical compounds capable of reproduction in standardized dosages, one of the factors to be determined in considering whether a substance had a currently accepted medical use. (26a); *See also* 57 Fed. Reg. 10499, 10505. (1992). In response to Mr. Olsen's inquiry based on the aforementioned definition, Administrator Bonner differentiated the schedule II placement of coca and opium from the schedule I placement of the marijuana on the grounds that the coca and opium plants were the basis for useful medications and that neither of the plants were used in their plant form as medicine. (26a). In both cases, medically useful alkaloids are extracted from the plant materials after which a pharmaceutical compound capable of reproduction in standardized doses are produced. *Id.* Unlike medications derived from opium and coca plants, he argued, the petition to reschedule marijuana did not involve the scheduling of any medically useful compound to be extracted from the plant material. *Id.*

Despite the previous Administrator's arguments to the contrary, Deputy Administrator Green, in his Final Order, admitted that marijuana is in fact the source of a medically useful compound, Dronabinol. *See* Final Order (3a). In order to avoid an obvious contradiction, Deputy Administrator Green successfully distracted the court by turning the argument to the issue of whether or not Dronabinol itself was a schedule I drug. (5a-6a). He argued that Dronabinol was scheduled in schedule II only when in sesame oil and encapsulated in soft gelatin capsules. Administrator Green found that the rescheduling of synthetic Dronabinol in a pharmaceutical compound had no effect on the scheduling of marijuana. (8a). On this basis, he

found the petition failed to raise any issue that justified the initiation of rescheduling proceedings. *Id.*

The unjustified findings by the Administrator contradict case law and prior D.E.A. conclusions and therefore were arbitrary and capricious. 5 U.S.C. § 706(a); *Chevron*, 467 U.S. at 843-44. The Administrator's finding that the rescheduling of THC in sesame oil had no effect on the rescheduling of marijuana contradicts D.E.A.'s prior finding that H.E.W. recommends moving THC to schedule II should it become the source of an approved new drug application. 50 Fed. Reg. 42186. Furthermore, during prior rescheduling hearings the D.E.A. agreed that synthetic THC, which D.E.A. claims is the main substance in Dronabinol, did not need to be controlled under the C.S.A. 40 Fed. Reg. 44164, 44168 (1975). During further proceedings, the Administrator took special note that synthetic THC was in schedule I. 51 Fed. Reg. 17477. Indicative of D.E.A.'s own confusion in this area, when answering the question whether marijuana has an accepted medical use, the Administrator measured the benefits of synthetic THC use against the negative effects of marijuana use. 57 Fed. Reg. 10500.

Inconsistent application of administrative precedent requires the agency to carefully spell out the basis of its decision when departing from prior norms. *See, Sect'y of Agriculture v. United States*, 347 U.S. 645, 652-53 (1954); *Food Marketing Institute v. Interstate Commerce Com.*, 587 F.2d 1285,1290 (D.C. Cir. 1978). Furthermore, when reviewing an agency decision under 5 U.S.C. § 706(2)(A) the court may accord a greater degree of scrutiny where an agency has been inconsistent. *Id.* In this case the D.E.A. has not provided any reasons for the inconsistency, therefore the decision should be set aside as being arbitrary and capricious. *Chevron*, 467 U.S. at 843.

II.

THIS COURT SHOULD GRANT CERTIORARI TO CONSIDER IF, BY DENYING MR. OLSEN'S FIRST AMENDMENT RIGHT TO PETITION THE GOVERNMENT FOR A REDRESS OF GRIEVANCES, THE DEPUTY ADMINISTRATOR'S ACTIONS VIOLATED THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT.

The Supreme Court has identified many constitutional rights as fundamental, and therefore these rights are entitled to heightened judicial protection. *See Eisenstadt v. Baird*, 405 U.S. 438 (1972). These include the fundamental guarantees of the Bill of Rights, such as the freedom of association, the right to petition the government for a redress of grievances, and the right to procedural fairness in regards to claims for governmental deprivations of life, liberty or property. *Planned Parenthood v. Casey*, 11 S. Ct. 2791, 2805, 505 U.S. 833 (1992); *Duncan v. Louisiana*, 391 U.S. 145, 147-148 (1968); *Quill v. Vaco*, 80 F.3d 716 (2d Cir. 1996). Through its arbitrary, capricious, and summary denial of Mr. Olsen's rescheduling petition, the D.E.A. has violated his fundamental right to fair process and his First Amendment right to petition the government for redress. *McDonald v. Smith*, 472 U.S. 479, 482 (1985). Furthermore, by denying these rights to Mr. Olsen, who represents the class of interested citizens that Congress sought to include in the schedule decision making process, the D.E.A.'s ruling violates the equal protection guarantees of the Fifth Amendment and the right to personal autonomy. *C.f., Massachusetts Board of Retirement v. Murgia*, 427 U.S. 307, 312 (1975); *Doe v. United States Civil Serv. Com'n.*, 483 F. Supp. 539, 562-574 (S.D.N.Y. 1980).

The First Amendment guarantees all citizens the right to petition the government for a redress of grievances. U.S. Const.,

Amend. I. This right is a fundamental concept of liberty. *McDonald*, 472 U.S. at 482. When the government, through its action denies a citizen of such a fundamental right, it may do so only if the action is narrowly tailored to serve a compelling government interest. *See Reno v. Flores*, 507 U.S. 292 (1993); *Brown v. Hartlage*, 456 U.S. 45, 53-54 (1982); *Steelworkers v. Sadlowski*, 457 U.S. 102, 111 (1982); *Murgia*, 427 U.S. at 312. The burden of proof in such a case is upon the government. *Id.* Fundamental rights are those explicit or implicitly derived from the constitution itself. *See San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 33-34 (1973).

The outright rejection of Mr. Olsen's rescheduling petition, without considering the evidence presented and without following statutorily mandated procedure denied the petitioner his First Amendment right to petition the government. *Steelworkers*, 457 U.S. at 111. The actions taken by the D.E.A. were not narrowly tailored and do not serve any compelling government interest. *See Id.* Administrative economy does not justify a complete refusal of the procedural process mandated by Congress. *See Schneider v. State*, 308 U.S. 147, 164 (1939). The administrator was required to seek medical and scientific advice from the secretary of H.H.S. 21 U.S.C. § 811. If, as respondents previously argued, Mr. Olsen's petition was denied on the grounds that it was procedurally defective, the Deputy Administrator should not have made scientific observations in his Final Order denying Mr. Olsen's petition. *NORML*, 559 F.2d at 757. The D.E.A.'s desire to prevent additional hearings and reconsideration of the rescheduling of marijuana is not a compelling government interest which justifies the D.E.A.'s violation of Mr. Olsen's First Amendment rights. *See Id.*

While the right to petition does not require that everyone should have a direct voice in all actions taken by our government, this court has recognized that where, as here, a government body

has either by its own decision or under statutory command determined to open its decision making process to public view and participation, the right to petition for redress is fundamental. *Madison School Dist. v. Wisconsin Employment Comm.*, 429 U.S. 178, 179 (1976); *San Filippo v. Bongiovanni*, 30 F.3d 424, 442 (3rd. Cir. 1994). Congress has mandated that public participation in the process by which drugs and other substances are controlled and scheduled is of paramount importance. *See NORML*, 559 F.2d at 757. Congress has expressly stated that interested citizens have a right to petition the D.E.A. for rescheduling of a drug. *Id.* By denying the petitioner his right to meaningfully present a petition, the D.E.A. has denied him of this fundamentally important First Amendment right. *See Madison*, 429 U.S. at 179. By depriving Mr. Olsen and others this right, the D.E.A. has violated the critical function of enabling a self governing people to both inform the government and to check abuses of government power. *McDonald*, 472 U.S. at 485.

III.

THIS COURT SHOULD GRANT CERTIORARI TO CONSIDER IF THE DENIAL OF MR. OLSEN'S PETITION, WITHOUT REGARD TO THE STATUTORY PROCESS MANDATED BY CONGRESS, DENIED MR. OLSEN'S RIGHT TO PROCEDURAL DUE PROCESS.

The Due Process clause guarantees that where the government deprives a citizen of a fundamental right, the citizen is guaranteed a fair procedure by which they may seek redress. *Bongiovanni*, 30 F.3d at 442. Where an agency, such as the D.E.A., significantly burdens a citizen's fundamental rights, it must at least assure accuracy and avoid arbitrariness. *Id.* Generally, the minimum process due in such a case is notice and the opportunity for hearing. *Doe*, 483 F. Supp. at 572.

The arbitrary and capricious manner with which the Deputy

Administrator denied Mr. Olsen's petition, denied Mr. Olsen of his constitutional right to procedural due process. *See Id.* The illogical and unreasonable manner in which Mr. Olsen's petition was denied deprived him of his right present new evidence. 21 U.S.C. § 811(a). The Congressional purpose of the statute under which Mr. Olsen was permitted to petition would be destroyed if the D.E.A. is allowed to summarily dismiss each petition without meaningful consideration of the evidence presented. *NORML*, 559 F.2d at 757.

Indicative of its history of contempt towards challenges to marijuana regulation, the D.E.A. has been quick to point out that petitioner has "frequently litigated issues related to the legal treatment of marijuana." *See* Respondent's Brief (42a); *See e.g., Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458, 1461-1465 (D.C.Cir. 1989), *cert. denied*, 495 U.S. 906 (1990); *Olsen v. Iowa*, 808 F.2d 652, 653 (8th Cir. 1986); *United States v. Rush*, 738 F.2d 497, 511-513 (1st Cir. 1984), *cert. denied*, 470 U.S. 1004 (1985); *State v. Olsen*, 315 N.W. 2d 1, 7-9 (Iowa 1982); *Olsen v. Drug Enforcement Admin.*, 776 F.2d 267, 268 (11th Cir. 1985), *cert. denied*, 475 U.S. 1030 (1986).

Judicial review pursuant to the Administrative Procedures Act encompasses a court's evaluation of the constitutionality of an agency's conduct. *Doe*, 483 F. Supp. at 572. The Congress, in its wisdom, set up a provision whereby any interested party could petition for rescheduling based upon changed circumstances or new evidence. 21 U.S.C. § 811(a). The scheduling of synthetic THC in schedule II and the evidence presented by petitioner, that H.E.W. views marijuana and synthetic THC to be one and the same, is exactly the type of new evidence which the administrator is required to consider. *NORML*, 559 F.2d at 754. While the D.E.A. may feel that petitioner is committing a wrongful act by exercising his constitutional right to petition the government, he is in fact

assisting the government by employing the mechanism Congress expressly provided: rescheduling based upon the careful consideration of new evidence as it arises. *Id.*

IV.

THIS COURT SHOULD GRANT CERTIORARI TO CONSIDER IF THE D.E.A.'S DENIAL OF MR. OLSEN'S PETITION CONSTITUTES AN INVASION OF PRIVACY IN THAT THE D.E.A. IS INTERFERING WITH SENSITIVE MEDICAL DECISIONS WITHOUT PROPER CONSTITUTIONAL JUSTIFICATION.

The right to make personal medical decisions has been held fundamental to a citizen's liberties under the substantive component of the Due Process Clause of the Fifth Amendment. *Casey*, 112 S. Ct. at 2805. This clause assures the citizenry that any deprivation of life liberty or property by a government entity will be attended by the appropriate legal processes. *Bowers v. Hardwick*, 478 U.S. 186, 192 (1986). This Court has found that the Due Process clause of the Fifth Amendment has substantive content, subsuming rights that are, to a great extent, immune from government regulation or proscription. *Id.* at 191. These cases have recognized implied rights that have little or no textual support in the constitutional language. *Id.* The rights which qualify for heightened judicial protection include fundamental liberties so implicit in the concept of ordered liberty that neither liberty nor justice would exist if they were sacrificed. *Palko v. Connecticut*, 302 U.S. 319, 325-24 (1937). Fundamental liberties have also been described as those that are deeply rooted in this nations history and tradition. *Moore v. City of East Cleveland*, 431 U.S. 479, 506 (1965) (White, J., concurring). The government may not infringe upon a fundamental liberty unless the infringement is narrowly tailored to serve a compelling government interest. *See Reno*, 507 U.S. 292.

The right to privacy has been found to encompass personal decisions relating to marriage, family, and education. *See Carey v. Population Services Int'l*, 431 U.S. 678, 684-85 (1977). While the constitution does not include any explicit mention of the right to privacy, this right has been judicially recognized. *Carey*, 431 U.S. at 684. In previous decisions, courts have found that smoking marijuana was not a fundamental right because it did not involve any important values inherent in questions involving marriage, procreation or child rearing. *See, NORML v. Bell*, 488 F. Supp. 123, 133 (D.D.C. 1980). While smoking marijuana itself may not be a fundamental right, the right to choose appropriate medication involves the right of every human being of sound mind and adult years to determine what should or should not be done with their own body. *Casey*, 112 S. Ct. at 2807; *Whalen v. Roe*, 429 U.S. 599, 600 (1977); *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 129 (1914). In the context of the medical use of marijuana, privacy rights are implicated.

In our system of a free government, where notions of individual autonomy and free choice are cherished, it is the individual who must have the final say in respect to decisions regarding his medical treatment in order to insure that the greatest possible protection is accorded his autonomy and freedom from unwanted interference with the furtherance of his own desires. *Rivers v. Katz*, 67 N.Y. 2d 485, 493(1986). This court has repeatedly recognized that the Constitution places limits on government interference with a person's most basic decisions about bodily integrity. *See e.g., Casey*, 431 U.S at 684; *Roe v. Wade* 410 U.S. 113, 152 (1973).

By foreclosing the rescheduling process, the D.E.A.'s decision amounts to government intrusion in matters involving the most intimate and personal choices a patient may make in a lifetime, choices central to personal dignity and autonomy and which are central to the liberty protected by the Fifth Amendment. U.S. Const. Amend IX; *Casey* 211 S. Ct. at 2807.

Because fundamental personal liberty interests are involved, they may not be abridged by the government simply on a showing that a regulatory statute has some rational relationship to the effectuation of a proper government purpose. *Poe v. Ullman*, 367 U.S. at 543. Where there is a significant encroachment upon personal liberty, the government may prevail only upon showing a subordinate interest which is compelling. *Bates v. City of Little Rock*, 361 U.S. 516, 524 (1960). The law must be shown to be necessary and not merely rationally related to the accomplishment of a permissible government policy. *McLaughlin, v. State of Florida*, 379 U.S. 184, 196 (1964) ; *See e.g., Schneider*, 308 U.S. at 161. Because the D.E.A. is unable to show any compelling purpose which is served by differentiating between the THC found in a plant and the same exact THC encapsulated in sesame oil and gelatin, the order refusing to reschedule marijuana to schedule II should be struck down because it unnecessarily infringes on medical THC users privacy rights. *Casey,* 112 S. Ct. at 2805.

V.

EQUAL PROTECTION.

The Due Process clause of the Fifth Amendment requires that federal legislation satisfy the same standards of equal protection of the law that are guaranteed by the Fourteenth Amendment. *See Buckley v. Valeo*, 424 U.S. 1, 93 (1976). Equal protection analysis in the Fifth Amendment area is the same as that under the Fourteenth Amendment. *Bolling v. Sharpe*, 347 U.S. 497, 450 (1954). It has long been recognized that when the government treats two classes of citizens differently under the law, the government must demonstrate that such dissimilar treatment is at least rationally related to a legitimate government purpose. *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440 (1985); *Hooper v. Bernalillo County Assessor*, 472 U.S. 612 (1985); *Plyer v. Doe*, 457 U.S. 202, 216 (1982).

A. This Court Should Grant Certiorari To Consider If The D.E.A.'s Dissimilar Treatment Of Medical THC Users Violates The Guarantees Of Equal Protection.

The arbitrary distinction drawn by D.E.A. between a legal user of synthetic THC and an illegal user of natural THC is not rationally related to any legitimate government purpose. *NORML*, 488 F. Supp. 134. The distinctions drawn by the D.E.A. with respect to the THC found in schedule I and the same THC found in schedule II must bear some rational relation to controlling psychotropic substances. *Hooper*, 472 U.S. at 618. The synthetic THC found in schedule II is structurally the same as the THC found naturally in marijuana. *See*, 51 Fed. Reg. 17,476. The only difference between the THC in schedule I and the THC in schedule II is that the substance in schedule II is encapsulated in gelatin and sesame oil. This distinction should be set aside as violative of the Equal Protection Clause because it is based on reasons totally unrelated to the pursuit of controlling substances. *See* 51 Fed. Reg. At 17,476; *Hooper*, 472 U.S. at 619-20; *NORML*, 488 F. Supp. at 134. *McDonald v. Board of Election Commissioners*, 394 U.S. 803, 809 (1969).

B. This Court Should Grant Certiorari To Consider Whether Or Not The D.E.A. Could Reasonably Believe That Differentiating Between THC Encapsulated In Gelatin And THC In The Plant Form Will Prevent Drug Abuse, And Thus, If That Distinction Is Rational.

This Court has held that where, as here, the legislative facts on which a classification is based could not reasonably be conceived to be true by the governmental decision maker the classification cannot be said to be rationally related to a legitimate government purpose. *Vance v. Bradley*, 440 U.S. 93, 111 (1979). The D.E.A. cannot reasonably believe distinguishing between a substance coated in gelatin and sesame oil and one

that is not, will prevent the abuse of the substance. *See* 51 Fed. Reg. 17476. Furthermore, both the courts and the D.E.A. have previously found that THC is the only reason the marijuana plant is controlled in schedule I. *Walton*, 514 F.2d at 204 n. 12. As the Appeals Court noted in 1991, one of the very purposes in placing a drug in schedule I is to raise significant barriers to prevent doctors from obtaining the drugs too easily. *A.C.T.*, 930 F.2d at 940. Now that the same substance which D.E.A. sought to prevent doctors from obtaining is a legally prescribable substance, in schedule II, the purpose no longer exists. 21 U.S.C.§ 811(a). To doggedly refuse to reschedule the marijuana plant to schedule II is a decision not rationally related to controlling THC and does not serve the purpose of drug abuse prevention. *See Walton*, 514 F.2d at 204.

C. This Court Should Grant Certiorari To Consider Whether The Destruction Of The Premise On Which Congress Placed Marijuana In Schedule I Makes The D.E.A.'s Refusal To Consider Rescheduling Unconstitutional, In That It Is Not Rationally Related To Any Legitimate Government Purpose.

Where a decision is predicated upon a particular state of facts, it can also be challenged by showing the Court that those facts are no longer true. *See Abie State Bank v. Bryan*, 282 U.S. 765 (1931). In a prior decisions, courts have noted that Congress's original placement of marijuana in schedule I was premised upon the fact that H.E.W. recommended it be placed there. *Bell*, 488 F. Supp. 134. The letter from H.E.W. suggesting that synthetic marijuana, which H.E.W. has placed in schedule II, is no different than the natural THC found in schedule I, coupled with the D.E.A.'s own recognition that both synthetic THC and natural THC are the same substance, should demonstrate to this court that the facts upon which marijuana was placed in schedule I have ceased to exist. (26a).

As previously noted, a drug must meet five criteria to remain in schedule I. 21 U.S.C. § 811(a). The most contested of these criteria is the requirement that the substance does not have an accepted medical use. *A.C.T*, 930 F.2d at 936. Like the coca and opium plants, the marijuana plant is now recognized as the source of a compound which is utilized as the basis of a useful medication. 51 Fed. Reg. 17476. The THC isomer, which has been judicially recognized as the ingredient which originally caused marijuana to be placed in schedule I, is now the source of a prescription drug. *Id.* F.D.A. approval of a drug is sufficient to establish the existence of an accepted medical use. *A.C.T. v. D.E.A.*, 930 F.2d 936 (1991); *Grinspoon* , 828 F.2d at 891-92. Furthermore, the F.D.A.'s study and testing of this substance, in order to give it the status of a new drug application, certainly satisfies the five criteria the D.E.A. must follow in determining accepted medical use. *Id.* All of these factual changes demonstrate that the D.E.A. based its decision not to reschedule marijuana, or even to hold hearings to consider new evidence, on moot and outdated information. *See Bell,* 488 F. Supp. at 135-136. Therefore, the decision is no longer rational. *Id.*

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A — FINAL ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT, (94-1605), FILED OCTOBER 3, 1996

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 94-1605
September Term, 1996

CARL ERIC OLSEN,

Petitioner

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent

PETITION FOR REVIEW OF AN ORDER OF THE DRUG ENFORCEMENT ADMINISTRATION

BEFORE: Williams, Sentelle, and Henderson, Circuit Judges.

JUDGMENT

This petition for review was considered on the record from an order of the Drug Enforcement Administration and on the briefs filed by the parties. The court has determined that the issues presented occasion no need for an opinion. See D.C. CIR. RULE 36(b). It is

ORDERED and ADJUDGED that the petition for review

be denied. Petitioner's rescheduling request was not supported by grounds sufficient to justify the initiation of rescheduling proceedings. See 21 C.F.R. § 1308.44(c).

The Clerk is directed to withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing. See D.C. CIR. RULE 41.

Per Curiam

FILED OCT 03 1996

APPENDIX B — FINAL ORDER OF THE D.E.A. DATED MAY 16, 1994

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of

PETITION OF CARL ERIC OLSEN

On Remand From the United States Court of Appeals for the District of Columbia Circuit, No. 93-1109

FINAL ORDER

This order is issued pursuant to an Order dated December 9, 1993, from the United States Court of Appeals for the District of Columbia Circuit which remanded the matter of a petition from Carl Eric Olsen to the Drug Enforcement Administration (DEA) for a ruling by the agency.

On September 6, 1992, Carl Eric Olsen (Petitioner) of Des Moines, Iowa, submitted a petition requesting that the controlled substance marijuana, be rescheduled from Schedule I to Schedule II of the Controlled Substances Act of 1970 (CSA). The Petitioner's grounds were based on his evaluation of two prior rescheduling actions by the Administrator. See Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules, 51 Fed. Reg. 17476 (1986) and Marijuana Rescheduling Petition, 57 Fed. Reg. 10499 (1992). On October 23, 1992, the-Administrator of Drug Enforcement, Robert C. Bonner, declined to accept his petition. The Petitioner subsequently filed for review of then-Administrator Bonner's decision with the United States Court of Appeals for the District of Columbia Circuit. The matter was

remanded by Order of that Court to the DEA for a ruling. Pursuant to that Court's Order, and 21 C.F.R. § 1308.44(c), the Deputy Administrator of the Drug Enforcement Administration has considered the matters before him and thereby renders his final decision.

In his Petition for rescheduling, the Petitioner alleged that marijuana need not have an accepted medical use in treatment in the United States in order to be rescheduled from Schedule I, but "it only needs to be shown that marijuana is a source for an accepted and useful medication". This contention was based on Petitioner's own analogies drawn from an earlier DEA marijuana rescheduling case, 57 Fed. Reg. 10499 (1992), and subsequent written statements made to the Petitioner by then-Administrator Bonner regarding coca leaves and opium plant material; and the Petitioner's incorrect contention that the DEA proposed to reschedule Dronabinol in a proposed rulemaking. See Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules, 50 Fed. Reg. 42186 (1985). It appears that Petitioner contends that this rescheduling action included delta-9-tetrahydrocannabinol (delta-9-THC), an ingredient in marijuana, and concluded that "since marijuana is now a source for an accepted and useful medication, it must now be rescheduled from Schedule I to Schedule II of the CSA".

The Deputy Administrator finds, for the reasons stated herein, that the grounds upon which the Petitioner relies are not sufficient to justify the initiation of proceedings for the transfer of marijuana from Schedule I to Schedule II of the CSA.

In July 1992, the Petitioner wrote then-Administrator Bonner regarding his final order of March 26, 1992, (57 Fed. Reg. 10499), in which the Administrator declined to reschedule

marijuana to Schedule II, and the apparent "unfair" classification of the marijuana plant as a Schedule I substance, while coca and opium plants remained in Schedule II. Then-Administrator Bonner replied by letter on August 17, 1992, and distinguished the pharmaceuticals or derivative compounds from each plant. Apparently, the Petitioner then created a theory, that given that the Schedule II opium and coca plants were a source for accepted medication, then if marijuana plants were a source for accepted medications it should also be a Schedule II substance. To further his argument, the Petitioner pointed to the rescheduled drug, which he called dronabinol, as having its source in marijuana. The Petitioner also alluded to inconsistencies of scheduling of delta-9-THC, a component of marijuana, between the CSA and certain multilateral international agreements.

When the CSA was created, Congress specified the initial scheduling of controlled substances and the criteria by which controlled substances could be rescheduled. 21 U.S.C. §§ 811-812. The DEA is bound, by law, to follow this mandate. Congress placed both the tetrahydrocannabinols, which includes delta-9-THC, and the plant marijuana into Schedule I when it enacted the CSA. See Pub. L. 91-513, § 202(c), Schedule I (c)(17) and (c)(10). Similarly, Congress placed opium poppy and straw and coca leaves into Schedule II. See Pub. L. 91-513, § 202(c), Schedule II (a)(3) and (a)(4). The legislative history indicates that marijuana was placed into Schedule I on its own merits and not because delta-9-THC could be extracted from it. H.R. Rep. No. 1444, 91st Cong., 2d Sess., pt. 1, at 12 (1970).

Whether or not marijuana is a source of delta-9-THC is irrelevant to the status of marijuana under the CSA. With regard to the classification of controlled substances, the Attorney General may, by rule, add to the established schedules or transfer

between such schedules and drug or other substance if [s]he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by subsection (b) of Section 812 for the schedule in which such drug is to be placed. 21 U.S.C. § 811(a)(1). The Attorney General has delegated this authority to the Administrator, who has redelegated it to the Deputy Administrator. See 28 C.F.R. §§ 0.100(b) and 0.104. (59 Fed. Reg. 23637 (May 6, 1994)).

In order for a substance to be placed into Schedule II, the Attorney General must find that: "(A) The drug or other substance has a high potential for abuse. (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. (C) Abuse of the drug or other substance may lead to severe psychological or physical dependence." 21 U.S.C. § 812(b)(2). Then-Administrator John C. Lawn previously determined that marijuana does not have a currently accepted medical use in treatment in the United States and as a result must remain in Schedule I. See Marijuana Rescheduling Petition, 54 Fed. Reg. 53767 (1989). Then-Administrator Lawn's final order was appealed to the United States Circuit Court of Appeals for the D.C. Circuit which returned the matter to the DEA for an explanation of the factors relied upon in determining "currently accepted medical use". See Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936 (D.C. Cir. 1991).

In response to the remand, then-Administrator Bonner issued a final order in which he determined that for a substance to have a "currently accepted medical use" the following must exist:

a. the drug's chemistry must be known and reproducible;

b. there must be adequate safety studies;

c. there must be adequate and well-controlled studies proving efficacy;

d. the drug must be accepted by qualified experts; and

e. the scientific evidence must be widely available.

Then-Administrator Bonner concluded that marijuana failed to meet all elements of the five-part test and, therefore, did not meet the statutorily prescribed criteria for a Schedule II substance. Marijuana Rescheduling Petition, 57 Fed. Reg. 10499 (1992); See Alliance for Cannabis Therapeutics v. DEA, et al., 15 F.3d 1131 (D.C. Cir. 1994) upholding the Administrator's decision.

Accordingly, the Deputy Administrator concludes that the Petitioner's contention that marijuana need not have an accepted medical use in treatment in the United States in order to be rescheduled from Schedule I to Schedule II of the CSA is not in accordance with law. DEA may only move a drug from Schedule I if there is a finding of "currently accepted medical use in treatment in the United States".

Although delta-9-THC is the principle psychoactive ingredient in marijuana, it can be synthesized and exist as a chemical. Delta-9-THC is a generic term which refers to four separate chemicals and two mixtures of chemicals, i.e., four stereochemical variants of the parent substance and two

racemates. One of the stereochemical variants, the (-) delta-9-trans-THC isomer, is the principle psychoactive ingredient in Cannabis sativa, L., or marijuana. That isomer is also the ingredient in a pharmaceutical product which has been shown to be safe and effective as an anti-emetic for certain patients receiving cancer chemotherapy, and is identified chemically as (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]-pyran-1-ol. The International Nonproprietary name (INN) and the U.S. Adopted Name (USAN) for that isomer of delta-9-THC is dronabinol.

With the development of scientific and medical evidence that demonstrated that a pharmaceutical product which contained dronabinol was safe and effective for the treatment of nausea and vomiting associated with cancer chemotherapy in certain patients, then-Administrator John C. Lawn rescheduled this pharmaceutical product from Schedule I to Schedule II. See 51 Fed. Reg. 17476 (1986). Only the pharmaceutical product was transferred from Schedule I to Schedule II, i.e., "dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration approved drug product". No rescheduling action was taken with regard to (-) delta-9-trans-THC, i.e., dronabinol, which remains in Schedule I of the CSA. Tetrahydrocannabinols, including delta-9-THC, one of the synthetic equivalents of the substances contained in the plant or resinous extractives of Cannabis (marijuana) are listed a. 21 C.F.R. § 1308.11(d)(25).

Tetrahydrocannabinols and all their isomers, including delta-9-THC, are also the subject of control by international agreement under the United Nations Convention on Psychotropic Substances, 1971, February 21, 1971, 32 U.S.T. 543, T.I.A.S. 9725, 1019 U.N.T.S.175. Cannabis, cannabis resin and extracts

and tinctures of cannabis are regulated as Schedule I substances under the United Nations Single Convention on Narcotic Drugs, 1961, March 30, 1961, 18 U.S.T. 1407, T.I.A.S. 6298, 520 U.N.T.S. 204. The United States is a party to both conventions.

Then-Administrator Lawn also discussed the United States international obligations in his Dronabinol in Sesame Oil and Encapsulated in a Soft Gelatin Capsule, rescheduling action. See 51 Fed. Reg. 17476 (1986). Since Article 7 of the Convention on Psychotropic Substances, 1971 has strict prohibitions on activities involving Schedule I drugs, in 1987, the United States Government initiated an action to have delta-9-THC transferred to Schedule II to allow the pharmaceutical product to be marketed. See U.N. Doc. E/CN.7/1990/4. Such a transfer was not inconsistent with the substance delta-9-THC remaining in the CSA Schedule I. Under Article 23 of the Convention on Psychotropic Substances, 1971, a party may adopt more strict or severe measures of control if desirable or necessary for the protection of the public health and welfare.

Under the CSA, the regulation of chemicals and the plant material are distinct from each other. The classification of delta-9-THC has no bearing on the classification of marijuana. Under the CSA, a proposed change in the schedule of either a tetrahydrocannabinol or the plant marijuana requires the Attorney General to proceed independently.

Petitioner apparently does not wish to look to the clear construct of the Controlled Substances Act, but to pose alternative theories of the Act. Under the CSA, drugs or other substances may be treated and classified differently, according to the enumerated statutory criteria. 21 U.S.C. § 812(b).

Appendix B

The Deputy Administrator reaffirms that marijuana does not have a currently accepted medical use in treatment in the United States and is thus appropriately listed as a Schedule I controlled substance. The Deputy Administrator finds nothing to support the petitioner's contention that since marijuana, coca, and opium are all plant materials they must be treated alike in the CSA. The Deputy Administrator further finds that the rescheduling of the pharmaceutical product "dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product", which contains the synthetic chemical ingredient (-) delta-9-trans-THC, did not require that either the plant marijuana or substance delta-9-THC be similarly rescheduled. The Petitioner's request is denied.

Stephen H. Greene, Deputy Administrator Dated: May 16, 1994

APPENDIX C — RELEVANT CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATIONS
(In Relevant Part)

A. First Amendment of the United States Constitution

Congress shall make no law . . . abridging..the right of the people . . . to petition the Government for a redress of grievances.

B. Fifth Amendment of the United States Constitution

No person shall be . . . deprived of life, liberty, or property, without due process of law . . .

C. Ninth Amendment of the United States Constitution

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

D. Fourteenth Amendment of the United States Constitution

No State shall . . . deny to any person within its jurisdiction the equal protection of the laws.

E. 5 U.S.C. 706 (1996)

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall —

> (1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be —

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

Appendix C

F. 21 U.S.C. 811 (1996) (in its entirety)

(a) Rules and regulations of Attorney General; hearing The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter.

Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule —

> (1) add to such a schedule or transfer between such schedules any drug or other substance if he —
>
> > (A) finds that such drug or other substance has a potential for abuse, and
> >
> > (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or
>
> (2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule. Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking

procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (C) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence

of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(C) Factors determinative of control or removal from schedules In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be

appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this subchapter to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services after consultation

with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(c) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall

(I) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)(A) If the Attorney General determines, after consultation with the Secretary of Health and Human Services, that proceedings initiated under recommendations made under paragraph (B) or (C)(I) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of

this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application

of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C) —

(I) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention, the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated

thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

(e) Immediate precursors

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) Abuse potential

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g) Exclusion of non-narcotic substances sold over the counter without a prescription; dextromethorphan; exemption of substances lacking abuse potential

Appendix C

(1) The Attorney General shall by regulation exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(h) Temporary scheduling to avoid imminent hazards to public safety

Appendix C

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). Such an order may not be issued before the expiration of thirty days from —

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling for up to six months.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) of this section with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

G. 21 U.S.C. 812 (1996)

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate

precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I. —

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II. —

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence . . .

SCHEDULE I

(C) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation,

which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation: . . .

(10) Marihuana.

H. 21 U.S.C. 877 (1996)

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

I. 21 C.F.R. 1307.03 (1996)

Any person may apply for an exception to the application of any provision of parts 1301-1308, 1311, 1312, or 1316 of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

Appendix C

J. 21 C.F.R. 1308.11 (1996)

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it . . .

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term 'isomer' includes the optical, position and geometric isomers): . . .

(17) Marihuana 7360

K. 21 C.F.R. 1308.12 (1996)

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or

independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: . . .

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine . . .

(f) Hallucinogenic substances.

(1) Dronabinol (synthetic) 7369

in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product (Some other names for dronabinol: (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3- pentyl-6H-dibenzo(b,d)pyran-1-ol, or (-)-delta-9-(trans)- tetrahydrocannabinol)

L. 21 C.F.R. 1308.44 (1996)

Initiation of proceedings for rulemaking

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

Appendix C

(b) Petitions shall be submitted in quintuplicate to the Administrator in the following form:

(Date)
Administrator, Drug Enforcement Administration
Department of Justice,
Washington, DC 20537.

Dear Sir: The undersigned ___ hereby petitions the Administrator to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act. Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

(NAME)
(STREET ADDRESS)
(CITY AND STATE)

Respectfully yours,

(SIGNATURE OF PETITIONER)

(c) Within a reasonable period of time after the receipt of a petition, the Administrator shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted, the reason therefor. The Administrator need not accept a petition for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the petitioner desires, he may amend the petition to meet the requirements of paragraph (b) of this section. If accepted for filing, a petition may be denied by the Administrator within a reasonable period of time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.

(d) The Administrator shall, before initiating proceedings for the issuance, amendment, or repeal of any rule either to control a drug or other substance, or to transfer a drug or other substance from one schedule to another, or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation and the Secretary's recommendations as to whether such drug or other substance should be so controlled, transferred, or removed as a controlled substance. The recommendations of the Secretary to the Administrator shall be binding on the Administrator as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Administrator shall not control that drug or other substance.

(e) If the Administrator determines that the scientific and

medical evaluation and recommendations of the Secretary and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or additional control over the drug or other substance, or substantial evidence that the drug or other substances should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings for control, transfer, or removal as the case may be.

(f) If and when the Administrator determines to initiate proceedings, he shall publish in the Federal Register general notice of any proposed rule making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to Sec. 1308.45. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the Federal Register. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

(g) The Administrator may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made.

M. 28 C.F.R. 0.100(b) (1996)

General functions.

The following-described matters are assigned to, and shall be

conducted, handled, or supervised by, the Administrator of the Drug Enforcement Administration: . . .

(b) Functions vested in the Attorney General by the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. This will include functions which may be vested in the Attorney General in subsequent amendments to the Comprehensive Drug Abuse Prevention and Control Act of 1970, and not otherwise specifically assigned or reserved by him.

N. 28 C.F.R. 0.104 (1996)

Redelegation of authority.

The Administrator of the Drug Enforcement Administration is authorized to redelegate to any of his subordinates or any of the officers or employees of the Immigration and Naturalization Service any of the powers and functions vested in him by this Subpart R.

APPENDIX D — F.D.A. LETTER TO PETITIONER DATED JULY 13, 1993

July 13, 1993

Dear Mr. Olsen:

This replies to your May 13, 1993, letter asking several questions about drugs.

It is true that a good many drugs useful in therapeutics can be extracted from herbs. Some drugs have an animal origin, e.g., many hormones. A synthetic drug is a drug that is made by chemically combining various starting materials to make the desired product. The product is then identical in all respects to the product isolated from a plant source. Such a product can be marketed under the same name. For example, cortisone is synthesized from a yam that grows in Mexico and it is identical to cortisone extracted from adrenal tissue.

A synthetic drug would be in the same schedule as its naturally occurring twin. For example, synthetic lysergic acid amide is in the same schedule as lysergic acid amide derived from the plant source.

Please let me know if I can be of further assistance on drug matters.

Sincerely yours,

Harold Davis
Consumer Safety Officer
CDER Executive Secretariat Staff (HFD-8)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

APPENDIX E — PETITIONERS LETTER TO D.E.A. ADMINISTRATOR DATED JULY 21, 1992

Post Office Box 4091
Des Moines, Iowa 50333
July 21, 1992

Robert C. Bonner, Administrator
Drug Enforcement Administration
Washington, D.C. 20537

Dear Mr. Bonner:

I just finished reading your decision on the Marijuana Rescheduling Petition, 57 FR 10499 (March 26, 1992). Your explanation of the scheduling criteria in the Controlled Substances Act (CSA) left me confused. By your definition, a substance in Schedule II is a scientifically established chemical compound capable of reproduction in standardized dosages. Of course, marijuana is not such a substance, it is a plant, not a drug.

Although you made no mention of the fact, the coca plant, from which cocaine is made, and the opium plant, from which morphine and heroin are made, are both in Schedule II of the CSA.

As I was reading your decision, I wondered how these two plants can be in Schedule II. These plants are subject to the same variances in chemistry as the marijuana plant. It seems like you are treating marijuana unfairly.

If Congress intended to rely on scientifically established chemistry and reproducible dosages, why did Congress include the coca and opium plants in Schedule II?

Appendix E

It seems to me that these plants should not be included in the CSA at all, because they will never fit into your definition of drugs, and I think your definition is correct as far as it goes. However, since Congress has decided to include them in the CSA, your definition is inadequate to explain them. I hope you will correct your definition, and not simply ignore this apparent inconsistency.

Thank you for your attention.

Sincerely, Carl Olsen, (515) 243-7351

APPENDIX F — D.E.A. ADMINISTRATOR BONNER'S LETTER TO PETITIONER DATED AUGUST 17, 1992.

August 17, 1992

Dear Mr. Olsen:

This is in response to your letter of July 21, 1992, regarding my decision with respect to the Marijuana Rescheduling Petition.

Your letter correctly states that one of the factors to be considered in determining whether a substance has a currently accepted medical use in treatment is that it is a scientifically established chemical compound capable of reproduction in standardized dosages. While you are also correct in noting that Congress placed coca and opium plant materials in Schedule II, your attempt to analogize those substances to marijuana, and to find inconsistency in their scheduling, fails.

In placing coca leaves and opium plant material in Schedule, II, Congress was very much aware that these plant materials have historically been recognized as the source for a variety of accepted and useful medications. Neither of these plants are used medicinally as plant material. In both instances, the medically active alkaloids are extracted from the plant material after which pharmaceutical compounds capable of reproduction in standardized dosages are produced. These compounds are the medications which may then be lawfully marketed in the United States. While indigenous populations in various parts of the world brew coca teas, chew coca leaves, and smoke opium for various purposes, these practices are not permitted in the United States under the Controlled Substances Act.

Unlike pharmaceuticals derived from opium and coca leaves, the petition to reschedule marijuana did not involve the

scheduling of any medically useful compound to be extracted from the plant material. Instead, the petition involved unsupported claims for the medical use of smoked marijuana. There is, therefore, no inconsistency in my finding that such claims did not make a case for accepted medical use in treatment in the United States.

Very truly yours,

Robert C. Bonner, Administrator of Drug Enforcement

APPENDIX G — PETITIONERS STATEMENT OF GROUNDS FOR RESCHEDULING, ACCOMPANYING HIS PETITION TO RESCHEDULE MARIJUANA DATED SEPTEMBER 6, 1992

PETITIONER'S STATEMENT OF GROUNDS FOR RESCHEDULING

The Controlled Substances Act (CSA), 21 U.S.C. §§ 801 et seq., contains five schedules, the first of which (Schedule I) contains substances which have no medical use in treatment in the United States, and the final four of which (Schedules II through V) contain substances which have medical use in treatment in the United States but which are available only by a physician's prescription. Marijuana is currently in Schedule I of the CSA.

On March 26, 1992, the Administrator made a final decision in a marijuana rescheduling petition, DEA No. 86-22, rejecting the finding of an administrative law judge that marijuana has medical use in treatment in the United States, and rejecting the administrative law judge's recommendation that marijuana be moved to Schedule II of the CSA. 57 FR 10499.

The essence of the decision was that marijuana is a plant and not a drug. The Administrator argued that the chemistry of the marijuana plant is complex, varies from plant to plant, and is incapable of reproduction in standardized dosages (attributes common to all plants), and that a drug is a scientifically established chemical compound capable of reproduction in standardized dosages.

The Administrator's decision has been appealed to the United States Court of Appeals for the District of Columbia by several parties seeking medical access to marijuana plants.

Appendix G

According to the Administrator, "the petition to reschedule marijuana did not involve the scheduling of any medically useful compound to be extracted from the plant material." The Administrator went on the say, "the petition involved unsupported claims for medical use of smoked marijuana." See Exhibit A.

As for other plants in Schedule II, the Administrator said, "In placing coca leaves and opium plant material in Schedule II, Congress was very much aware that these plant materials have historically been recognized as the source for a variety of accepted and useful medications." The Administrator went on to say, "Neither of these plants are used medicinally as plant material." See Exhibit A.

It must follow from the Administrator's explanation that marijuana need not have an accepted medical use in treatment in the United States in order to be rescheduled from Schedule I to Schedule II of the CSA, it only needs to be shown that marijuana is a source for an accepted and useful medication.

On October 11, 1985, the Administrator proposed to reschedule dronabinol to Schedule II of the CSA. 50 FR 42186 (October 18, 1985); 21 C.F.R. § 1308.12(f)(1) (1991). Dronabinol is the synthetic equivalent of the isomer of delta-9-tetrahydrocannabinol which is the principle psychoactive substance present in Cannabis Sativa L., marijuana. 50 FR 42186 (October 18, 1985).

Dronabinol is the U.S. Adopted Name (USAN) for the substance (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo [b,d] pyran-1-ol or (-)-delta-9-(trans)-tetrahydrocannabinol, the principle psychoactive substance in

Appendix G

Cannabis sativa L., marijuana. 50 FR 42186 (October 18, 1985). It has the empirical formula C21H30O2 with molecular weight of 314.45. 1989 Physician's Desk Reference, page 1859.

On May 24, 1991, the United Nations Economic and Social Council (ESCOR) rescheduled delta-9-tetrahydrocannabinol from Schedule I to Schedule II of the 1971 Convention on Psychotropic Substances. U.N. Doc. E/CN.7/1991/26. Report of the Commission on Narcotic Drugs on its thirty-fourth session, U.N. Doc. E/1991/24, Supp. No. 4. The United States is a party to that international convention pursuant to the Psychotropic Substances Act of 1978 (Pub. L. 95-633, November 10, 1978). 50 FR 42186 (October 18, 1985).

Since marijuana is now a source for an accepted and useful medication, it must now be moved from Schedule I to Schedule II of the CSA.

Respectfully submitted,

Carl Eric Olsen
Post Office Box 4091
Des Moines, Iowa 50333
(515) 243-7351

APPENDIX H — RESPONDENT'S BRIEF BEFORE THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA *(footnotes omitted, except for note 4, which is directly pertinent)*

CASE BEING CONSIDERED FOR TREATMENT
PURSUANT TO RULE 34(j) OF THE GENERAL RULES

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 94-1605

CARL ERIC OLSEN,

Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

PETITION FOR REVIEW OF AN ORDER OF THE
DRUG ENFORCEMENT ADMINISTRATION

BRIEF FOR THE RESPONDENT

STATEMENT OF THE ISSUE

Whether the Drug Enforcement Administration properly rejected the petitioner's theory that marihuana plants should be moved from Schedule I to Schedule II of the Controlled Substances

Act because marihuana plants are a source of an accepted

and useful medication when the petitioner's theory was based solely upon language in an informal letter and was contradicted directly by the plain language of the Controlled Substances Act.

STATUTES AND REGULATIONS

Except for those already included in the Addendum to the Petitioner's Brief, the pertinent statutes and regulations are set forth in an addendum bound with this brief.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

In response to the growing drug problem in the United States, Congress in 1970 passed the Controlled Substances Act, 21 U.S.C. 801 et seq. ("CSA"). The CSA classifies various hazardous drugs into five schedules. Id. 812. Restrictions upon use and access to a particular drug vary based upon the drug's schedule status in the CSA. Drugs in Schedule I are subject to more severe restrictions than drugs in the other schedules. See Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., 930 F.2d 936, 937 (D.C. Cir. 1991). Congress placed marihuana in Schedule I of the CSA.1 21 U.S.C. 812(c), Schedule I(c)(10).

Although Congress made the initial scheduling decisions, the CSA specifically permits the Attorney General to add a substance to a schedule, transfer a substance from one schedule to another or remove a substance from the schedules entirely. Id. 811(a). The Attorney General may only transfer a substance to a different schedule if she "finds that such drug or other

substance has a potential for abuse" and makes findings that the drug or substance meets the requirements for the new schedule. Id. The findings required for placing a substance in a particular schedule are listed in 21 U.S.C. 812(b). The Attorney General has delegated the authority to reschedule controlled substances to the Administrator of the Drug Enforcement Administration ("DEA"). 28 C.F.R. 0.100(b). The Drug Enforcement Administrator ("Administrator") has further delegated this authority to the Deputy Administrator. 28 C.F.R. 0.104.

For over 20 years, various groups and individuals have asked DEA to exercise its authority to move marihuana from Schedule I to a less restrictive schedule or to remove marihuana from the CSA schedules entirely. See Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., 15 F.3d 1131 (D.C. Cir. 1994); Alliance for Cannabis Therapeutics, 930 F.2d at 937; National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d 735 (D.C. Cir. 1977); National Org. for the Reform of Marijuana Laws v. Ingersoll, 497 F.2d 654 (D.C. Cir. 1974).

Despite these efforts, in March of 1992, the Administrator issued a final order denying a petition to reschedule marihuana from Schedule I to Schedule II of the CSA. See 57 Fed. Reg. 10,499 (1992).

The Administrator relied upon the language of the CSA in making his determination. Under the CSA, a drug or substance may not be placed in Schedule II absent findings that:

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence. 21 U.S.C. 812(b)(2)(A)-(C).

In the Administrator's final order, he concluded that the marihuana plant had no currently accepted medical use and thus could not be placed in schedule II. 57 Fed. Reg. at 10,499. The Administrator applied a five-part test for determining whether a substance had a currently accepted medical use:

(1) the drug's chemistry must be known and reproducible;

(2) there must be adequate safety studies;

(3) there must be adequate and well-controlled studies proving efficacy;

(4) the drug must be accepted by qualified experts; and

(5) the scientific evidence must be widely available. 57 Fed. Reg. at 10,504-10,507.

After reviewing the evidence in the record, the Administrator found that marihuana could not satisfy a single one of these criteria. Id. at 10,507. These findings, as well as other findings of fact and conclusions of law, resulted in the denial of the marihuana rescheduling petition.

Appendix H

II. THE CURRENT PROCEEDINGS

On July 21, 1992, the petitioner sent a letter to then-Administrator Robert C. Bonner in which he raised several questions about the Administrator's final order. In the letter, the petitioner appeared to agree with the Administrator's finding that marihuana, as a plant, failed to satisfy the first part of the test for determining a currently accepted medical use because a plant such as marihuana is not a scientifically established compound capable of reproduction in standard dosages. A. 1.3 The petitioner's letter then asked why coca and opium plants (the sources of cocaine, morphine, and heroin) were placed in Schedule II. Id. If, the petitioner reasoned, coca and opium plants are subject to the same scientific variances as marihuana plants, then DEA is "treating marijuana unfairly." Id. The petitioner suggested either removing all plants from the CSA schedules because they "will never fit into your definition of drugs" or changing the definition to account for the inconsistency in the treatment of the different plants. Id.

On August 17, 1992, Administrator Bonner sent the petitioner a response to his letter. A. 5. In the response, the Administrator rejected the petitioner's attempt to analogize marihuana plants to coca and opium plants. Id. The Administrator explained that when Congress placed coca leaves and opium plant materials in Schedule II, it was aware that these plants had been recognized historically as the source for a variety of accepted and useful medications. Id. The plants contain medically active alkaloids that can be extracted and used to produce pharmaceutical compounds capable of reproduction in standardized doses. Id. In contrast, the Administrator pointed out that the recent attempts to reschedule marihuana were not grounded on claims that medically useful compounds could be

extracted from marihuana, but rather that smoking marihuana itself produced medical benefits. Id. Thus, the Administrator found the scheduling decisions to be reconcilable. Id. at 5-6.

The petitioner, proceeding pro se, then filed a formal request for the rescheduling of marihuana pursuant to 21 U.S.C. 811 and 21 C.F.R. 1307.03.4 A. 2-4. In his petition, he drew an analogy from language in the Administrator's letter of August 17, 1992. He reasoned that if coca leaves and opium plants could be placed in Schedule II because they are sources of accepted and useful medications, then marihuana plants could be placed in schedule II if marihuana is shown to be "a source for an accepted and useful medication." A. 3. The petitioner then noted that dronabinol, a synthetic equivalent of the isomer which is the principle psychoactive substance in marihuana, has been rescheduled to Schedule II. Id. Because marihuana is the source of an accepted and useful medication, dronabinol, the petitioner reasoned that marihuana must be moved to Schedule II of the

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4. The petitioner has frequently litigated issues related to the legal treatment of marihana. He challenged several criminal convictions by arguing that marihana smoking was protected by the free exercise clause of the First Amendment and the equal protection clause of the Fourteenth Amendment. See Olsen v. Iowa, 808 F.2d 652, 653 (8th Cir. 1986); United States v. Rush, 738 F.2d 497, 511-513 (lst Cir. 1984), cert. denied, 470 U.S. 1004 (1985); State v. Olsen, 315 N.W.2d 1, 7-9 (Iowa 1982). Additionally, the petitioner has brought numerous civil actions seeking to obtain judicial authorization to use marihuana. See Olsen v. Drug Enforcement Admin., 878 F.2d 1458, 1461-1465 (D.C. Cir. 1989), cert. denied, 495 U.S. 906 (1990); Olsen v. Drug Enforcement Admin., 776 F.2d 267, 268 (llth Cir. 1985), cert. denied, 475 U.S. 1030 (1986); Olsen v. State, Civ. No. 83-301-E, 1986 WL 4045, at *1 (S.D. Iowa March 19, 1986). The petitioner also participated in the administrative proceedings where the DEA considered a petition to reschedule marihuana from Schedule I to Schedule II of the CSA. See 54 Fed. Reg. at 53,767.

CSA. Id. at 4. The petitioner then requested that the Administrator reschedule marihuana from Schedule I to Schedule II of the CSA. Id. at 2.5

The Administrator initially refused to accept the rescheduling petition because dronabinol is a wholly synthetic substance and is not obtained from marihuana. A. 7. However, after the petitioner appealed, DEA voluntarily asked this court to remand the petition for a ruling. This court remanded the petition in an Order dated December 9, 1993. See Olsen v. Drug Enforcement Admin., No. 93-1109 (D.C. Cir. Dec. 9, 1993).

On May 16, 1994, Deputy Administrator Stephen H. Greene issued a nine-page final order denying the petition. A. 17. The final order explained that Congress placed marihuana in Schedule I. A. 19-20. It rejected the petitioner's analogy, finding that marihuana can only be moved from Schedule I if there is a finding that marihuana has a "currently accepted medical use in treatment in the United States." A. 22. The order acknowledged that (-)delta-9-trans-THC isomer, the principal psychoactive ingredient in marihuana, is also the ingredient in a pharmaceutical product that has proven to be a safe and effective anti-emetic for patients receiving cancer chemotherapy. Id. However, the order noted that only a very specific synthetic dronabinol product was rescheduled to Schedule II — "dronabinol ("synthetic) in sesame oil and encapsulated in a soft gelatin capsule" in a drug product approved by the Food and Drug Administration ("FDA"). A. 23. The order further stated that the regulation of plants and chemicals under the CSA is distinct and that the CSA requires the independent evaluation of each individual controlled substance. A. 24. The final order reaffirmed that marihuana plants have no currently accepted medical use in treatment and found that the rescheduling of one

pharmaceutical product did not require DEA to transfer marihuana plants or any other substance to Schedule II. A. 24-25.

The petitioner has appealed the final order to this court pursuant to 21 U.S.C. 877.

SUMMARY OF THE ARGUMENT

Congress placed marihuana in Schedule I of the CSA and this decision has been consistently approved by the courts. The petitioner is incorrect in asserting that marihuana must be moved from Schedule I to Schedule II if it is a source of an accepted and useful medication. The plain language of the CSA requires that a substance itself must have a currently accepted medical use before it may be moved from Schedule I to Schedule II. The petitioner has failed to provide any evidence to suggest that the marihuana plant itself has a currently accepted medical use. Under the CSA, the rescheduling of synthetic dronabinol in a pharmaceutical product has no effect on the scheduling of the marihuana plant. Thus, the petitioner's request for rescheduling failed to raise any issue that justified the initiation of rescheduling proceedings.

The petitioner is also incorrect in asserting that dronabinol was moved from Schedule I to Schedule II. Only one specific pharmaceutical product containing synthetic dronabinol has been moved to Schedule II: synthetic dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a FDA-approved drug product. Although the petitioner now seeks to challenge the legality of the rule rescheduling this pharmaceutical product and argues that dronabinol should have been rescheduled in its entirety, he did not raise these issues before DEA. These issues should not be considered for the first time by this court.

Appendix H

ARGUMENT

I. STANDARD OF REVIEW

Any interested person may submit a petition to DEA requesting that DEA reschedule a controlled substance. 21 U.S.C. 811(a); 21 C.F.R. 1308.44(a). However, a petition that is accepted for filing "may be denied by the Administrator within a reasonable time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings." 21 C.F.R. 1308.44(c). The Administrator relied upon this provision in denying the petition in the instant case.A. 18-19.

In reviewing the Administrator's decision, findings of fact, "if supported by substantial evidence, shall be conclusive." 21 U.S.C. 877. Additionally, DEA's action may be set aside if it was arbitrary, capricious, an abuse of discretion or contrary to law. 5 U.S.C. 706. However, when reviewing an administrative agency's interpretation of a statute, the court must give effect to the unambiguously expressed intent of Congress. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-843 (1984). If the statute is silent or ambiguous, the court is to determine whether the agency's interpretation is based upon a permissible construction of the statute. Id. at 843. The court may not substitute its own judgment for a reasonable interpretation made by the administrator of an agency. Id. at 844.

Appendix H

II. CONGRESS, DEA, AND THE COURTS HAVE ALL FOUND THAT MARIHUANA IS PROPERLY IN SCHEDULE I OF THE CSA AND MUST REMAIN THERE UNTIL IT SATISFIES THE CRITERIA IN 21 U.S.C. 812(b).

Congress made the initial decision to place marihuana in Schedule I. 21 U.S.C. 811(c). This decision was made after careful consideration. The legislative history of the CSA demonstrates that Congress was sensitive to the arguments of those who advocated the deregulation of marihuana.6 See H. Rep. No. 1444, 81st Cong., 2d Sess. 12-13, reprinted in 1970 U.S.C.C.A.N. 4566, 4577-4578. Congress also sought the advice of the Department of Health, Education, and Welfare ("HEW") before making a scheduling determination for marihuana. After considering this information, Congress placed marihuana in Schedule I so that the drug would be subject to the CSA's "most stringent controls." Id. at 14, reprinted in 1970 U.S.C.C.A.N. at 4579.

Since the passage of the CSA, numerous individuals have attempted to challenge the decision of Congress to place marihuana in Schedule I as being irrational or unconstitutional. These challenges have been uniformly rejected by the federal courts. See, e.g., United States v. Greene, 892 F.2d 453, 455-456 (6th Cir. 1989), cert. denied, 495 U.S. 935 (1990); United States v. Fogarty, 692 F.2d 542, 547 (8th Cir. 1982), cert. denied, 460 U.S. 1040 (1983); United States v. Middleton, 690 F.2d 820, 823 (11th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); National Org. for the Reform of Marijuana Laws v. Bell, 488 F. Supp. 123, 139-141 (D.D.C. 1980) (three judge court).

In rejecting constitutional challenges to the initial classification of marihuana, courts frequently have pointed out

that 21 U.S.C. 811(a) provides the Attorney General with the authority to reclassify marihuana if scientific information later demonstrates that Schedule I is not the appropriate schedule. See, e.g., Greene, 892 F.2d at 456; Fogarty, 692 F.2d at 548; Middleton, 690 F.2d at 823; National Org. for the Reform of Mariiuana Laws, 488 F. Supp. at 141. DEA, on behalf of the Attorney General, recently conducted lengthy proceedings pursuant to 811(a) and found that marihuana should not be moved from Schedule I because the plant has no currently accepted medical use and because it is not safe for use, even under medical supervision. These decisions were approved by this court.

III. DEA PROPERLY FOUND THAT THE PETITION WAS NOT SUFFICIENT TO JUSTIFY ADDITIONAL RESCHEDULING PROCEEDINGS BECAUSE THE PETITION WAS PREMISED ON THE INCORRECT BELIEF THAT A SCHEDULE I DRUG MUST BE RESCHEDULED IF IT IS THE SOURCE OFAN ACCEPTED AND USEFUL MEDICATION.

In seeking to reschedule marihuana from Schedule I to Schedule II, the petitioner made a rather creative argument based upon several flawed premises. DEA properly detected the flaws in the petitioner's logic and found that the petition raised no credible issue that would justify additional proceedings to reschedule marihuana.

A. THE PETITIONER'S ARGUMENT

The petitioner's argument was based entirely upon his construction of language contained in then-Administrator Bonner's response to an earlier letter sent by the petitioner. In

response to the petitioner's query about why marihuana plants are in Schedule I while coca leaves and opium plants are in Schedule II, the Administrator stated that: In placing coca leaves and opium plant material in Schedule II, Congress was very much aware that these plant materials have historically been recognized as the source for a variety of accepted and useful medications. A. 5. The petitioner then seized upon the Administrator's language as "general rules of statutory construction." Pet. Br. 9. Using the newly created rules of statutory construction as his springboard, the petitioner took an additional logical leap by inferring that if marihuana were found to be a "source for an accepted and useful medication," it must be moved from Schedule I to Schedule II. A. 3-4.

Having created a new theory of statutory construction, the petitioner proceeded to apply it with apparently successful results. He noted that a synthetic equivalent of the principal psychoactive ingredient in marihuana recently had been moved from Schedule I to Schedule II. Since marihuana was the source of this "accepted and useful medication," the petitioner concluded that marihuana "must now be moved from Schedule I to Schedule II of the CSA." A. 4.

B. THE CSA DOES NOT MANDATE THAT A SCHEDULE I DRUG MUST BE RESCHEDULED IF IT IS THE SOURCE OF AN ACCEPTED AND USEFUL MEDICATION BUT REQUIRES DEA TO MAKE INDIVIDUAL FINDINGS ABOUT A PARTICULAR DRUG PRIOR TO RESCHEDULING IT.

The premise of the petitioner's argument is that if a Schedule I controlled substance is the source of an accepted and useful medication, the Schedule I substance must be placed into the

schedule that contains the accepted and useful medication. This premise is in direct conflict with the language of the CSA.

As discussed previously, Congress itself decided to place marihuana in Schedule I. See National Org. for the Reform of Mariiuana Laws, 488 F. Supp. at 141. Although marihuana may be rescheduled:

> [t]he clear meaning of section 812(c) is that Congress intended marijuana to remain in Schedule I until such time as it might be reclassified by the Attorney General on the basis of more complete scientific information about the drug. In such a reclassification hearing, the statutory criteria would be the guides to determining the most appropriate schedule for marijuana.

Id. Thus, under the CSA, marihuana plants should remain in Schedule I unless and until more complete information indicates that placement in a different schedule is more appropriate.

The CSA's language concerning the rescheduling of a controlled substance does not suggest that a substance should be rescheduled merely because it is the source for an accepted and useful medication. The CSA states that in order to transfer a controlled substance from one schedule to another, the Attorney General must make "with respect to such druct or other substance the findings prescribed by" 21 U.S.C. 812(b) "for the schedule in which such drug is to be placed." 21 U.S.C. 811(a)(1)(B) (emphasis added). Under 812(b), "a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other

substance." 21 U.S.C. 812(b) (emphasis added). Thus, contrary to the petitioner's representations, the plain language of the CSA states that in order for DEA to reschedule marihuana plants from Schedule I to Schedule II, DEA must make the appropriate findings with respect to marihuana plants.

The CSA states that DEA cannot move a drug from Schedule I to Schedule II unless it finds, inter alia, that the "drug or other substance" to be rescheduled has a currently accepted medical use. 21 U.S.C. 812(b)(2)(B). The CSA's language does not state or imply that this criterion can be satisfied by a substance that is the source of a drug with a currently accepted medical use. Additionally, the petitioner has produced no authority to indicate that any controlled substance being considered for rescheduling ever has been found to have a currently accepted medical use merely because it was the source of an "accepted and useful medication." Thus, marihuana plants themselves must have a "currently accepted medical use" in order to satisfy the rescheduling criterion in 21 U.S.C. 812(b)(2)(B). Because the petitioner's request raised no doubts about DEA's recent findings that marihuana plants have no currently accepted medical use, DEA acted properly when it declined to initiate proceedings to reschedule marihuana plants.

The petitioner's novel theory that a source of an accepted and useful medication must be moved out of Schedule I is rooted in a misinterpretation of the then-Administrator's letter. Although the letter attempted to explain why Congress may have chosen to place coca leaves and opium plants in Schedule II, nothing in the letter states or even suggests that Congress, the Attorney General, DEA or the courts have adopted a general rule of statutory construction that whenever a plant is the source of an accepted and useful medication, it must be rescheduled.

Further, nothing in the letter suggests that its text was intended to serve as some type of binding administrative interpretation of the CSA. The letter was simply an informal response to a citizen's question about DEA's recent refusal to reschedule marihuana. Such an informal unpublished letter that does not even purport to be a final agency action cannot have a binding effect on DEA. See Independent Ins, Agents of Am., Inc. v. Ludwig, 997 F.2d 958, 962 (D.C. Cir. 1993) (finding that six unpublished letters of Comptroller of the Currency provided no reliable evidence of Comptroller policy); USAA Fed. Sav. Bank v. McLaughlin, 849 F.2d 1505, 1508-1509 (D.C. Cir. 1988) (finding that informal unpublished letter in response to individuals specific inquiry did not constitute definitive statement of Department of Labor policy).

Although there may be some arguable inconsistency between the scheduling of marihuana plants and the scheduling of coca leaves and opium plant material, such would not be irrational or contrary to the CSA. Congress placed all of these substances in their CSA schedules. These scheduling decisions have been upheld as rational and constitutional. See, e.g., United States v. Whitley, 734 F.2d 1129, 1141 (6th Cir. 1984) (not irrational or unreasonable for Congress to classify cocaine as narcotic substance under Schedule II of CSA even though cocaine is non- narcotic central nervous system stimulant); National Org. for the Reform of Mariluana Laws, 488 F. Supp. at 140 (even if marihuana does not fall within literal reading of Schedule I, classification in Schedule I is rational and furthers regulatory purposes of Congress). DEA and the courts have conducted reviews of the scheduling decision and have determined that marihuana should remain in Schedule I. See Alliance for Cannabis Therapeutics, 15 F.3d at 1137. Since the petitioner presented no new medical, scientific or other

information to suggest that circumstances have changed since DEA's last review, DEA acted properly when it refused to conduct additional hearings in response to the petitioner's request to move marihuana from Schedule I to Schedule II.

IV. THE ADMINISTRATOR PROPERLY DENIED THE PETITION BECAUSE IT RELIED ON THE INCORRECT ASSUMPTION THAT DRONABINOL HAS BEEN MOVED TO SCHEDULE II WHEN IN FACT ONLY A SINGLE PHARMACEUTICAL PRODUCT HAS BEEN MOVED TO SCHEDULE II.

In addition to relying on a mistaken interpretation of the CSA, the petitioner also appeared to rely incorrectly upon the premise that all forms of dronabinol have been rescheduled from Schedule I to Schedule II. DEA did not promulgate such a sweeping rule. Rather, DEA has merely rescheduled one particular pharmaceutical product that has been approved by the FDA.

In May of 1985, the FDA approved a new drug application for Marinol Capsules, which was submitted by Unimed Incorporated. Marinol Capsules contain specified quantities of synthetic dronabinol in sesame oil and encapsulated in round soft gelatin capsules. See 50 Fed. Reg. 42,186 (1985). DEA then issued a notice of proposed rulemaking seeking to move this pharmaceutical product (and no other Schedule I substance) to Schedule II. Id. After following appropriate rulemaking procedures, on May 13, 1986, the Administrator issued a rule:

> to transfer U.S. Food and Drug Administration (FDA) approved drug products that consist of synthetic dronabinol

> in sesame oil encapsulated in soft gelatin capsules from Schedule I into Schedule II of the Controlled Substances Act (CSA). Dronabinol is the synthetic equivalent of the isomer of delta-9- tetrahydrocannabinol (THC) which is the principal psychoactive substance in Cannabis sativa L., marijuana. This action is based on a finding that U.S. Food and Drug Administration approved drug products which contain dronabinol fit the statutory criteria for inclusion in Schedule II of the CSA. . . . This rule does not affect the Schedule I status of any other substance, mixture or preparation which is currently included in 21-CFR 1308-11(d)(21), Tetrahydrocannabinols.

51 Fed. Reg. 17,476 (1986) (emphasis added).

This rule clearly indicates that only a very specific substance ("Marinol") was moved from Schedule I to Schedule II. See 21 C.F.R. 1308.12(f)(1). DEA did not transfer any other dronabinol products to Schedule II nor did it transfer all tetrahydrocannabinols or all cannabis products to Schedule II. See 51 Fed. Reg. at 17,476 ("Dronabinol and all mixtures, compounds and preparations thereof, except dronabinol in sesame oil and encapsulated in soft gelatin capsules in a FDA approved product, remain in Schedule I"). Thus, marihuana plants and tetrahydrocannabinols remain listed in Schedule I. See 21 C.F.R. 1308.11(d)(18) and 1308.11(d)(26).

In rejecting the petitioner's request in this case, DEA's final order correctly explained that dronabinol remains in Schedule I

of the CSA and that only Marinol was placed in Schedule II in 1986. A. 23. Faced with this explanation and the clear language of DEA's final rule of 1986, the petitioner has changed his argument. He now claims that dronabinol should have been placed in Schedule II when the pharmaceutical product Marinol was rescheduled in 1986. Thus, for the first time on appeal, the petitioner appears to be challenging the propriety of the DEA rule that rescheduled Marinol from Schedule I to Schedule II. See 51 Fed. Reg. at 17,476.

The petitioner did not seek this relief below. Nothing in his petition to DEA suggested that he was challenging the validity of the rescheduling of Marinol. Similarly, nothing in the petition suggested that he was petitioning DEA to reschedule dronabinol or some other substance to Schedule II. The petition only asked DEA to reschedule marihuana. See A. 2-4. To the extent that petitioner seeks relief that he did not request in the proceedings before DEA or challenges the validity of a rule he did not previously challenge, he should be precluded from raising these issues for the first time on appeal because he has failed to exhaust his administrative remedies. See Cutler v. Hayes, 818 F.2d 879, 890-891 (D.C. Cir. 1987); Randolph-Sheppard Vendors of America v. Weinberger, 795 F.2d 90, 104-105 (D.C. Cir. 1986). The court should require the petitioner to exhaust his administrative remedies on these additional issues because (1) it is necessary to discourage this prolific petitioner from frequently and deliberately flouting the administrative process by raising new issues for the first time on appeal; (2) DEA should have the first opportunity to consider these issues and apply its technical expertise in order to protect its autonomy from judicial intrusion; (3) the record before this court on these issues is incomplete because the issues were not discussed in the administrative proceeding; and (4) judicial economy will be

enhanced if the administrative proceedings obviate the need for judicial involvement. See Fertilizer Institute v. United States Envtl. Protection Agency, 935 F.2d 1303, 1312-1313 (D.C. Cir. 1991); Cutler, 818 F.2d at 890-891. The petitioner is free to bring a separate challenge to the validity of the rulemaking that rescheduled Marinol or to petition DEA to reschedule dronabinol or some other substance. However, no purpose would be served by remanding the instant case to address either challenge. Even assuming arguendo that the petitioner could prevail on either challenge, he could not achieve the ultimate relief he sought in this proceeding -- rescheduling of marihuana plants -- because the language of the CSA clearly indicates that the scheduling of other substances has no bearing on the proper scheduling of marihuana plants.

CONCLUSION

For the foregoing reasons, this court should affirm DEA's final order denying the petitioner's request.

Respectfully submitted,
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